

REMARKS

Attorney for applicants has carefully reviewed the outstanding Office Action on the above-referenced application. Applicants have amended Claims 26-44 and added Claim 45.

The Examiner has rejected Claims 26-28 and 33-44 under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. "Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp. 2561-2574, 15 Dec. 2000. Claims 26-44 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Niederauer et al. reference in view of Vyakarnam et al. U.S. Patent No. 6,306,424. These claim rejections are respectfully traversed for the following reasons.

Amended independent Claim 26 relates to a "method for repairing a defect area at the gradient junction of cartilaginous tissue and bony tissue," which includes "providing a composite scaffold with a porous discrete ceramic layer, a porous discrete polymer layer, and an interface region attaching the discrete ceramic layer to the discrete polymer layer, where in the interface region, a portion of the polymer layer is at least partially infused into a portion of the ceramic layer mechanically interlocking the ceramic and polymer layers." The "interface region [is] situated between the discrete ceramic layer and the discrete polymer layer." See amended Claim 26. Amended Claim 26 further includes "boring a receptacle space in the gradient junction at the site of the injury to receive the scaffold, the gradient junction being that of articular

cartilage,” and “placing and securing the scaffold in the receptacle space with the ceramic layer adjacent to the bony tissue and the polymer layer adjacent to the cartilaginous tissue.” See amended Claim 26.

Applicants note that support for this amendment can be found in the specification and the originally filed drawings (e.g., Figures 1 and 2). For example, paragraph [0022] of the published application states that “The present invention relates to bi- or multi-layered scaffolds with a porous, bioabsorbable polymer layer attached to a porous ceramic layer via a porous transitional interface.”

One of the inventors of the present invention, Mr. Yufu Li, has prepared a Declaration Under 37 C.F.R. 1.132 (“Declaration”) to distinguish the scaffold disclosed in the present invention from the scaffold disclosed in the Niederauer et al. reference. Specifically, Mr. Yufu Li prepared drawings illustrating the scaffold disclosed in the present invention and the scaffold disclosed in the Niederauer et al. reference (see the enclosed Exhibit to the Declaration).

The enclosed Exhibit shows a front view and three sectional views of the present invention in the drawings labeled “Our Structures” and “Cross section of our structure.” Specifically, and as stated in the Declaration, the sectional view labeled “100% Porous Pure Ceramic Layer” is taken along the horizontal axis at an area above the interface region, the sectional view labeled “Porous Ceramic/ Porous Polymer interface” is taken along the horizontal axis at the interface region, and the sectional view labeled “100% Porous Pure Polymer Layer” is taken along the horizontal axis at an area below the interface region.

As can be clearly seen from these drawings, the scaffold recited in amended Claim 26 has at least two discrete layers and an interface attaching the layers to each other. One discrete layer includes only ceramic, while the other discrete layer includes only polymer. A portion of the polymer layer is shown as being at least partially infused into a portion of the ceramic layer at the interface region. Thus, there is a gradual transition between the ceramic and polymer layers, which correlates to the gradual transition that is displayed between the juncture of cartilage and bone.

It is respectfully submitted that the Niederauer et al. reference does not anticipate or make obvious the present invention as recited in amended Claim 26. The scaffold disclosed in the Niederauer et al. reference is prepared from layers of polylactic/polyglycolic acid (PLG) and either Bioglass particles or calcium sulfate. The scaffold disclosed in the Niederauer et al. reference is significantly different from the novel scaffold recited in amended Claim 26. The scaffold disclosed in the Niederauer et al. reference may include a ceramic and a polymer. However, the ceramic and the polymer are simply blended with each other (see the Niederauer et al. reference, third and fourth paragraphs on the left column of page 2563) and the phases glued together (see the Niederauer et al. reference, sixth paragraph on the left column of page 2563).

Referring to the enclosed Exhibit of the Declaration, Mr. Yufu Li has drawn three sectional views of the scaffold disclosed in the Niederauer et al. reference (see the drawing labeled "Prior art Structures"). Specifically, and as stated in the Declaration, the sectional views are taken along the horizontal axis at three different portions of the scaffold (i.e., a top portion, a central portion, and a bottom portion). As

shown in the enclosed Exhibit, each of these layers includes both ceramic and polymer.

Because the ceramic and the polymer are simply blended with each other and the phases glued together, each layer of the scaffold disclosed in the Niederauer et al. reference is essentially a composite, which is bi-phasic (includes both ceramic and polymer). Thus, the scaffold disclosed in the Niederauer et al. reference does not include any discrete layers of ceramic or polymer, as shown in the enclosed Exhibit. This is in direct contrast to the present invention, wherein the scaffold includes a porous discrete ceramic layer and a porous discrete polymer layer that are connected at the interface region, where a portion of the polymer layer is at least partially infused into a portion of the ceramic layer mechanically interlocking the ceramic and polymer layers (see amended Claim 26).

There is no disclosure or suggestion in the Niederauer et al. reference of "a porous discrete ceramic layer, a porous discrete polymer layer, and an interface region attaching the ceramic layer to the polymer layer, where in the interface region, a portion of the polymer layer is at least partially infused into a portion of the ceramic layer mechanically interlocking the ceramic and polymer layers" as recited in amended Claim 26.

In addition, the ceramic layer of the present invention is placed "adjacent to the bony tissue," while the polymer layer is placed "adjacent to the cartilaginous tissue." See amended Claim 26. As previously discussed, the ceramic and the polymer disclosed in the Niederauer et al. reference are simply blended with each other and glued together. Because of the compounded layers disclosed in the Niederauer et al.

reference, both ceramic and polymer would be undesirably positioned adjacent to bony tissue and to cartilaginous tissue.

In view of the distinctions discussed above, it is respectfully submitted that the Niederauer et al. reference fails to disclose or suggest the method recited in amended Claim 26.

With respect to the Vyakarnam reference, it does not disclose or suggest any interaction between a polymer layer and a ceramic layer, much less "an interface region attaching the ceramic layer to the polymer layer, where in the interface region, a portion of the polymer layer is at least partially infused into a portion of the ceramic layer mechanically interlocking the ceramic and polymer layers," as recited in amended Claim 26. Therefore, applicants' attorney respectfully submits that the Vyakarnam reference, whether considered individually or in combination with the Niederauer et al. reference, does not anticipate or make obvious the present invention as recited in amended Claim 26.

In the foregoing circumstances, amended Claim 26 is believed to be in condition for allowance. Because Claims 29, 30, 33, 34, 39, and 42 and new Claim 45 depend, either directly or indirectly, from amended Claim 26, they are also believed to be in condition for allowance. Nevertheless, applicants' attorney notes that the dependent claims recite additional novel features of the present invention. For instance, new Claim 45 requires that "the interface region exhibits a gradual transition between the ceramic and polymer layers."

Amended independent method Claims 27 and 28 are very similar in scope to that of amended independent method Claim 26. In such circumstances, amended Claims 27 and 28 are patentably distinguishable over the Niederauer et al. and the Vyakarnam references for the reasons discussed above. Accordingly, amended independent Claims 27 and 28 are believed to be in condition for allowance.

Claims 31, 35, 36, 40, and 43 depend, either directly or indirectly, from amended Claim 27, while Claims 32, 37, 38, 41, and 44 depend, either directly or indirectly, from amended Claim 28. Accordingly, Claims 31, 32, 35-38, 40, 41, 43, and 44 are also believed to be in condition for allowance.

In view of the foregoing amendments and remarks, applicants' attorney respectfully requests reexamination and allowance of pending Claims 26-44, and examination and allowance of new Claim 45. If such action cannot be taken, the Examiner is cordially invited to place a telephone call to applicants' attorney in order that any outstanding issue may be resolved without the issuance of a further Office Action.

A fee in the amount of \$120.00 for a one-month Extension Petition is believed to be due. The Petition authorizes the Examiner to charge this \$120 fee to Deposit Account No. 503571. No additional fees are believed to be due as a result of the submittal of this Amendment. If any such fees are due, the Examiner is hereby

Application No. 09/892,993
Amendment dated June 18, 2008
Reply to Office Action mailed February 20, 2008

authorized to charge them to Deposit Account No. 503571.

Respectfully Submitted,

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Dated: June 18, 2008